

REMARKS

Claims 1, 2, 11-13 and 33 have been cancelled. Claims 3-10, 14-32, 34 and 35 have been amended and claims 36-38 have been newly submitted. No new matter has been added. Thus, claims 3-10, 14-32, 34 and 35 remain pending in the application. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1-3 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner asserts that the term "producing" is not defined explicitly in the specification or implicitly through its usage. *See 4/9/07 Office Action*, p. 2. Claims 4-10 and 33 also stand rejected due to their dependence upon claims 1-3.

In this regard, claims 1, 2 and 33 have been cancelled. Also, claim 3 has been amended use the term "*generating*" instead of the term "*producing*" and to depend upon newly submitted claim 36.

Newly submitted independent claims 36 and 37 use the terms "*generating*" and/or "*generator*" instead of the term "*producing*". The terms "*generating*" and "*generator*" are supported by the description as originally filed, for example in page 8, lines 29-30, and from page 9, line 5, to page 10, line 6, where a first system for generating droplets (generator of droplets) is described.

Therefore, it is respectfully submitted that the features recited in newly submitted independent claims 36 and 37 are supported and described in the specification as originally filed and accordingly these new claims 36 and 37 are believed to meet with the requirements of 35 U.S.C. § 112, second paragraph. Because claims 3-10 depend from and, therefore, include all of

Page -12-

the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Claims 1-6 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,630,796 to Bellhouse et al. ("Bellhouse"). *See 4/9/07 Office Action*, p. 2.

Claims 1 and 2 have been cancelled and claim 3 has been amended to depend upon newly submitted claim 36.

New claim 36 recites a method for needleless injection of a liquid substance into a target biological tissue, the method comprising "generating droplets of the liquid substance; accelerating the droplets of the liquid substance at a velocity sufficiently high to inject the droplets of the liquid substance into the target biological tissue" and "directing the droplets of the liquid substance toward a surface of the target biological tissue at the sufficiently high velocity to inject the droplets of the liquid substance into the target biological tissue; wherein generating the droplets of the liquid substance comprises *pressurizing a reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through at least one micro-orifice to thereby produce a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets*"

In contrast, Belhouse discloses a needleless syringe which has (a) a chamber for containing a pressurized gas, (b) a capsule containing particles of therapeutic agent and sealed with a membrane and (c) a nozzle. In operation, release of the pressurized gas bursts the membrane. Once the membrane has been burst, the particles are carried by the flow of gas through the nozzle at a velocity sufficient to deliver the particles of therapeutic agent into a patient's skin.

The needleless syringe according to Belhouse delivers a therapeutic agent under the form of powder and comprises, for that purpose, a capsule containing particles of the therapeutic agent. On the contrary, the present patent application discloses a syringe for needleless injection of a liquid substance in the form of droplets of the liquid substance. Thus, the syringe according to the present invention includes a generator of liquid droplets.

The examiner cites column 4, lines 14-16 of Belhouse which describes particles made of tiny spherical shells of, for example, up to 100 μm diameter in which solid or liquid drugs are encapsulated. This does not constitute a means for producing droplets of liquid substance since Belhouse states in column 4, lines 16-19, that if the encapsulating shell has a controlled permeability, this may provide an additional means of providing a slow drug release rate after delivery. This passage confirms that the shells are not burst before delivery to form droplets of liquid.

Belhouse is silent on the teaching of generating droplets of the liquid substance before injection. Therefore, it is respectfully submitted that Belhouse does not teach or suggest *"pressurizing a reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through at least one micro-orifice to thereby produce a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets,"* as recited in claim 36.

At least for the above reasons, it is respectfully submitted that new independent claim 36 is not anticipated by Bellhouse and is allowable. Since claims 3-6 depend directly or indirectly upon newly submitted claim 36, it is respectfully submitted that these claims are also allowable.

Claims 1-35 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Bellhouse in view of U.S. Patent No. 6,808,246 to Long. The Examiner concedes that Bellhouse does not

show the mechanism for generating the liquid droplets. However, the Examiner cites Long to cure this deficiency. *See 4/9/07 Office Action*, p. 3.

It is respectfully submitted that Long does not cure the deficiencies of Bellhouse. Claims 1, 2 and 33 have been cancelled, new independent claims 36 and 37 have been submitted, and claim 3 has been amended to depend upon new claim 36.

New claim 37 recites a needleless syringe for injecting a liquid substance into a target biological tissue comprising "a generator of droplets of the liquid substance for generating droplets of the liquid substance" and "a droplet accelerator for accelerating the droplets of the liquid substance toward a surface of the target biological tissue in order to inject the accelerated droplets into the target biological tissue; wherein the generator of droplets comprises: a reservoir of the liquid substance to be injected; at least one micro-orifice through which the liquid substance from the reservoir is supplied; and a source of pressure for *pressurizing the reservoir of the liquid substance and forcing the liquid substance through the at least one micro-orifice to thereby produce a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets.*"

Long discloses a device for removing unwanted ink from a continuous inkjet printer. In operation, the print head of the printer heats ink to produce ink filaments through a plurality of nozzles. The ink filaments are broken down into droplets by a resistive element. The device comprises a porous element having a slit and to which a negative pressure is applied. The porous element captures misdirected droplets of ink, i.e. those which have fallen from the traced path to the print medium. The negative pressure is used for removing the captured droplets.

As described in the newly submitted independent claims, a reservoir of liquid substance is pressurized so as to force the liquid substance through at least one micro-orifice. In this manner,

a jet of the liquid substance is generated. This jet of liquid subsequently becomes unstable and is transformed into droplets of the liquid substance. On the contrary, Long describes breaking down ink filaments from the nozzles into droplets by means of a resistive element (see column 3, lines 26-29 and lines 44-46).

Therefore, it is respectfully submitted that Long fails to describe or suggest the feature of the newly submitted independent claims 36 and 37, consisting of pressurizing a reservoir of liquid substance to force the liquid substance through at least one micro-orifice to thereby generate a jet of the liquid substance which becomes unstable and is transformed into a plurality of droplets.

It is also respectfully submitted that Long does not constitute "analogous art" to the present invention.

Section 103 requires that obviousness be determined on the basis of whether at the time the invention was made a person of ordinary skill in the art to which the subject matter pertains would have found the claimed invention as a whole obvious. Although one of ordinary skill in the art is presumed to be aware of all prior art in the field to which the invention pertains, he is not presumed to be aware of prior art outside that field and the field of the problem to be solved, *i.e.*, non-analogous art. Accordingly, upon considering prior art as a basis for a *prima facie* case of obviousness one must determine the scope or bounds of the knowledge of one of ordinary skill in the art, *i.e.*, the analogous art presumably known by one of ordinary skill in the art.

In *In re Wood*, 599 F.2d 1032, 202 USP, the CCPA held:

The determination that a reference is from a non-analogous art is therefore

Page -16-

twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved.

In this respect, it is respectfully submitted that a patent related to a start-up and shut down of a continuous inkjet print head is outside the field of an invention related to a needleless syringe for the subcutaneous injection of droplets of liquid substance. The problems to be solved are also different; in the present invention the problem to be solved is to efficiently inject droplets of a liquid substance in a patient's biological tissue while the invention of Long is related to improve the quality of an image printed on a surface of a printing medium, not beneath that surface, by preventing misdirected and misshapen ink drops to be ejected from the print head.

In *In re Horn*, 203 USPQ 969 (CCPA 1979), the court also stated that:

For the teachings of a reference to be prior art under 103, there must be some basis for concluding that the reference would have been considered by one skilled in the art working on the pertinent problem to which the invention pertains.

It is respectfully submitted that an inventor working on the problem of efficiently injecting droplets of a liquid substance in a patient's biological tissue would have no reason to consider any technology to improve the quality of an image printed on a surface of a printing medium by preventing misdirected and misshapen ink drops to be ejected from the print head.

At least for the above reasons, it is respectfully submitted that independent claims 36 and 37 are not rendered obvious by Bellhouse in view of Long, taken separately or in combination. Therefore, it is respectfully submitted that newly submitted claims 36 and 37 are allowable in the present patent application. Because claims 3-10, 14-32, 34, 35 and 38 depend directly or indirectly upon allowable claims 36 and 37, it is respectfully submitted that these claims are also allowable.

RECEIVED
CENTRAL FAX CENTER

OCT 09 2007

CONCLUSION

In light of the foregoing, Applicants respectfully submit that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated: October 9, 2007

By: 

Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP

150 Broadway, Suite 702

New York, New York 10038

Tel: (212) 619-6000

Fax: (212) 619-0276

Page -19-